

**REMARKS/ARGUMENTS**

As an initial matter, Applicants wish to thank the Examiner for indicating claims 41-43, 68, and 78-80 as allowable in the Office Action dated October 7, 2003. (Office Action at 6.)

I. **Status of the Claims**

By the present amendment, originally presented claims 1-80 have been cancelled without prejudice or disclaimer and new claims 81-263 have been added. Support for the present amendment may be found in the specification as originally filed, including the original claims. Therefore, no new matter has been added.

New claims 81-148 and 204-263 incorporate the subject matter of original claims 41-43, 68, and 78-80, indicated as allowable in the Office Action. The new independent claims include subject matter corresponding to the allowable, original independent claims, is shown in the following table:

New Claims	Support
81 and claims dependent therefrom	Original Claims 41 & 42
85 and claims dependent therefrom	Original Claims 32 & 78
131 & 132 and claims dependent therefrom	Original Claim 68

Additionally, as recited in new claims 149-203 and 229-263, the rate of irradiation is not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation. Support for this limitation may be found in the specification as originally filed, for instance, pages 20-22. The undersigned notes that this limitation is the same as that recited in

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independent claim 1 of U.S. Patent No. 6,682,695, which issued from U.S. Patent Application No. 10/197,248.

## II. Response to the Grounds of Rejection

In the outstanding Office Action, the Office made the following grounds of rejection:

- A) Claims 1, 11-14, 33, 44-46, 54, 59, and 6 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 6,171, 549 (“Kent”);
- B) Claims 1-3, 5-7, 11-14, 24-31, 33-35, 39, 44-46, 54, and 59-67 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by *Microbiological Studies on Drugs and Their Raw Materials* (“Sakai et al.”);
- C) Claims 5,9, 15-19, 24-31, 33, 47, 54 and 59 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,989,498 (“Odland”);
- D) Claims 60-67 and 69-77 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,730,933 (“Peterson”);
- E) Claims 2, 32-39, 40, 44, 45, 49, 54 and 55 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 4,727,027 (“Wiesehahn et al.”);
- F) Claims 2 and 48 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,637,451 (“Ben-Hur et al.”);
- G) Claims 1, 2, 5, 9-14, 32-36, 39, 44-46 and 48-53 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,712,086 (“Horowitz et al.”) in view

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of Kent; and

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H) Claims 4-8, 20-36, 39, 40, 44, 47 and 55-57 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Peterson in view of Kent.

Applicants respectfully traverse these rejections, and respectfully submit that the rejections are moot for at least the following reason. Originally presented claims 1-88, as discussed above, have been cancelled. New claims 81-148 and 204-263 have been added, which encompass the subject matter indicated as allowable by the Examiner, i.e., original claims 41-43, 68, and 78-80. Since these claims recite subject matter indicated as allowable in the Office Action, the prior art of record fails to teach or to suggest the invention as recited in new claims 81-148 and 204-263 for at least the reasons noted by the Examiner in the Office Action with respect to original claims 41-43, 68, and 78-80 (Office Action at 6). Therefore, these grounds of rejection should be withdrawn.

Additionally, regarding new claims 149-203 and 229-263, the undersigned respectfully submits that the prior art of record fails to teach or to suggest methods for sterilizing biological materials, as presently claimed, wherein the rate of irradiation is not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation. Therefore, for at least this reason, new claims 149-203 are allowable over the prior art of record.

As indicated above, this limitation, *viz.*, the rate of irradiation is not constant and comprises a rate of between 0.1kGy/hr to 3.0kGy/hr for at least a portion of the period of

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irradiation and a rate of at least 6.0kGy/hr for at least another portion of the period of irradiation, is the same as that recited in independent claim 1 of U.S. Patent No. 6,682,695 which issued from U.S. Patent Application No. 10/197,248. As noted by the Examiner in that related application, the prior art fails to teach or to suggest methods for sterilizing biological materials wherein the dose rate is increased during the course of irradiation (see U.S. Patent Application No. 10/197,248, Office Action dated July 7, 2003). Therefore, new claims 149-203 and 229-263 are allowable over the prior art of record, since the prior art of record fails to teach or suggest methods wherein the rate is not constant and includes the specific rates enumerated in claims 149-203 and 229-263.

### **CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the application is in condition for allowance. If the Examiner believes that any additional changes would place the application in better condition for allowance, the Examiner is invited to contact the undersigned agent, Timothy M. Speer, at the telephone number listed below. Favorable consideration and prompt allowance are earnestly solicited.

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To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,  
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**Date: February 9, 2004**

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